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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,398	07/17/2000	MELENIE J MURPHY	124-781	4847

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/06/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,398

Applicant(s)

MURPHY ET AL.

Examiner

Ja-Na A Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-20 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed May 20, 2002 has been entered. Claim 4 has been amended. Claim 36 has been cancelled. Claims 4-20 are under consideration in this office action.

Withdrawal of Rejections

2. The rejection of claims 4-20 and 36 under 35 U.S.C. 103(a) as being obvious over Squirrell (WO 96/02666) in view of Sanders (WO 94/064931).

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for determining the susceptibility of a bacteria to a reagent which method comprises the steps of: (i) assaying for adenylate kinase released by lysis of bacteria from a culture containing said reagent; (ii) assaying for adenylate kinase released by lysis of bacteria from one or more of the recited cultures; and (iii) comparing results of the assays of step (i) and (ii) to determine the susceptibility of bacteria to said reagent.

The claims recite that merely assaying the culture as the only active step in the claims without defining the assaying procedures. Thus the claims fails to recite specifically how the assay of the culture is performed or what the results of the assays are. The specification teaches: exposing the appropriate bacterial cells to a reagent; subjecting the bacterial culture to lytic reagent so as to lyse the cells; extracting adenylate kinase from a sample; exposing the cells to any reagents necessary for assaying the adenylate kinase such as luciferin and if necessary separating the bacterial cells or preserving the cells and providing suitable growth media. See pages 8-12 of the instant specification. The specification teaches that the all the steps may result in determining the susceptibility of bacteria.

The specification does not teach examples of said method comprised of vague recitation of assaying the cultures. Thus, simply mentioning assaying of cultures in the claims does not provide enablement for a method that has no recited steps; neither does the recitation provided guidance on what the necessary steps are and the necessary reagents combinations are which will comprise a complete method of determination. Moreover, the claims do not define method steps for how to determine

susceptibility. The specification does not teach how to achieve a method for determining the susceptibility of a bacteria to a reagent which method comprises the steps of: (i) assaying for adenylate kinase released by lysis of bacteria from a culture containing said reagent; (ii) assaying for adenylate kinase released by lysis of bacteria from one or more of the recited cultures; and (iii) comparing results of the assays of step (i) and (ii) to determine the susceptibility of bacteria to said reagent. Thus, the method recited in the claims does not teach the inclusion of the other necessary steps and the claims are rejected.

4. Claims 4-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rejected for being vague and indefinite for the recitation of "susceptibility of a bacteria." The metes and bounds of susceptibility in the claim cannot be ascertained. It is unclear how to define susceptibility, i.e., is susceptibility only the amount of adenylate kinase produced or not produced or growth in the presence or absence of reagents, it is not clear what applicant intends to embrace. The language is not as precise as it could be in view of the specification. Applicant is asked to clearly state what applicant is intending to claim.

5. Claims 14 and 17 are drawn to a method according to claim 4 for determining the sensitivity of a bacteria, however the claims are not commensurate in scope to claim 4 which is drawn to determining susceptibility of a bacteria.

Clarification is required to overcome the rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 4-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Squirrel (WO 96/02666).

Squirrel teaches a method for determining the presence and/or amount of a microorganism and its intracellular material in a sample characterized by exposing the sample to a specific bind agent that has been immobilized upon a solid surface, thus allowing capture, the adenylate kinase activity assayed and the released such that a further sample of test material may be analyzed (page 3). The invention relates to improvements in which adenylate kinase activity is used as a label or marker for microorganism capture techniques (page 2). The adenylate kinase activity can work with colorimetric assays, conventional capture assays and other well-known immunoassay (page 2-3). Using the adenylate kinase format with adenylate kinase and ATP depleted reagent, the number of microorganisms present in a sample can be determined (page 3). Targeting adenylate kinase instead of ATP allows for higher sensitivity detection not seen with other methods (page 1). The adenylate kinase system allows for a linear correlation between the protein and the bacterial count (page

2). The method also describes single reagent use with the adenylate kinase testing methods (page 7). Contaminants can affect the adenylate kinase production (page 8), thus acting as an antibiotic and making the bacteria susceptible to death. In order to distinguish between target cells and other cells, separate assays can be run treating with a nonionic detergent capable of disrupting cells (page 10). In order for adenylate kinase to be analyzed, disruption of the cell, i.e., lysis, is necessary to allow the intracellular material to be released (page 9-10). Other reagents capable of cell lyses are also taught such as lysozymes, detergents ultrasonic generation, and osmotic shock (page 10).

The recitation "a method for determining the susceptibility of a bacteria to a reagent" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). There are no method steps which recite particular calculations or the determination of specific assay results to define susceptibility, thus any assaying for adenylate kinase satisfies the claims.

It should be noted that step (ii) is in the alternative, thus as long as one or more toe the cultures of (a), (b) or (c) are assayed, then the prior art meets the limitations of the claims.

Thus Squirrell teach assaying for adenylate kinase released by lysis of bacteria from a culture containing and not containing a reagent wherein a similar culture to that of a step (i) by that does not contain said reagent has its results compared to determine the susceptibility of bacteria to said reagent.

Response to Arguments

7. Applicant's arguments filed May 20, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The rejection of claims 4-20 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained.

Applicants state that the amendment of claim 4 obviates the rejection, thus the rejection should be withdrawn. However, the newly amended claim still omits method steps. The claims now recite the steps of "assaying for adenylate kinase released by lysis of bacteria from a culture that may or may not contain a reagent. However, the claims do not recite what method steps for necessary to assay for adenylate kinase. There is no step that comprises adding reagent to the culture. There is no step that describes how to assay for adenylate kinase or determine the amount produced. There

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are still no contact steps that contacts adenylate kinase released which a detection agent. There is detection step that recites how the adenylate kinase is detected, i.e., a detection of results to be compared. There is no positive recitation of a step that recites how to compare results. Method steps must be positively recited. See *Ex parte Erlich* 3 USPQ 101.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The rejection of claims 4 and 17-20 under 35 U.S.C. 103(a) as being unpatentable over Squirrell (WO 96/02666) in view of Sanders (WO 94/064931).

Applicant argues that neither Squirrell nor Sanders teach or suggest method of determining susceptibility of bacteria to reagents. However, it would have been prima facie obvious at the time of applicants invention to have modify the method of determining the susceptibility of a bacteria to a reagent as taught by Squirrell wherein the modification incorporates using bacteriophage particles released at the end of phage replication as taught by Sander et al., when the prior art already teaches assaying the lysed components. One would have a reasonable expectation of success since Sanders et al., teach that the phages provide faster and more sensitive results of bacteria in any environment when compared with non-phage systems. Moreover, the

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lysis of the cell walls of bacteria when new phage particles are released at the end of the phage replication cycle is well known in the art to release of cellular contents and capable of being assayed.

Applicants argue that "claim 4 makes it clear that the 'different point in time' refers to taking two measurements and that these measurements should be compared in order to determine susceptibility of the bacteria to reagents. However, the claim language is in the alternative and states that one or more the cultures can be assayed, thus the culture of step (i) at a different point in time is an optional limitation. And as long as any one of the cultures from a) b) or c) are assayed, then the claim limitation is met. Thus the prior art meets the limitation and is therefore maintained.

There is no limitation in the claims that refers to taking two measurements and that these measurements should be compared in order to determine susceptibility of the bacteria to reagents, therefore applicants argument is not persuasive and the rejection is maintained.

Applicant argues that the combination of Squirrell and Sanders would result in a method of detecting or quantifying bacteria and not a method of determining the sensitivity of bacteria to reagents. However, the claims are drawn to a method which does not define or recite how susceptibility is determined. Thus as long as the prior art assays the culture, then it meets the claim limitations. Moreover, it appears that susceptibility is defined by specification as the bacteria's ability to grow in the presence of the reagent, the method of Squirrell and Sanders teach assaying the bacterial culture in the presence of a reagent as compared to the culture not in the presence of the


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reagent. Thus, the prior art teaches the instant claims by comprising the same steps of assaying the cultures. Therefore, the rejection is maintained.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na A Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
July 29, 2002


MARK NAVARRO
PRIMARY EXAMINER